DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

OCT - 7 2002

Mr. Hui Fen Li
President
New York Healthy Herbs, Inc.
135-23 40th Road
Suite 2F
Flushing, New York 11354

Dear Mr. Li:

This is in response to your letter of September 15, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that New York Healthy Herbs, Inc. intends to market as a dietary supplement a product named **Youth Plus**. This letter is to advise you that this product appears to be adulterated under the Federal Food, Drug, and Cosmetic Act (the Act) and if adulterated, may not be lawfully marketed in the United States.

The product **Youth Plus** contains human placenta. Human placenta is not a dietary ingredient under section 201(ff)(1) of the Act. It is not a vitamin, a mineral, an herb or botanical, or an amino acid (section 201(ff)(1)(A-D) of the Act), nor is it a concentrate, metabolite, constituent, extract, or combination of any ingredient above (section 201(ff)(1)(F) of the Act). It also is not a "dietary substance for use by man to supplement the diet by increasing the total dietary intake (section 201(ff)(1)(E) of the Act), nor is it a concentrate, metabolite, constituent, extract, or combination of any dietary ingredient. Human placenta also is not a food under section 201(f) of the Act. Given that human tissue is not "food" or a "dietary ingredient," and that it may transmit human disease, a dietary supplement that contains it is adulterated under the Act (sections 402(a)(1), 402(f)(1)(A), and 402(a)(3) of the Act). The introduction or delivery for introduction into interstate commerce of any food that is adulterated is prohibited (section 301(a) of the Act).

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Please contact us if we may be of further assistance.

Sincerely yours,

John B. Foret

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New York District Office, Office of Compliance, HFR-NE140

New York Healthy Herbs Inc.
135-23 40th Road Ste. 2F Flushing, NY 11354
Tel: 718-888-1997 Fax: 718-321-1455

Food and Drug Administration
Division of Compliance and Enforcement/ONPLDS
Center for Food Safety and Applied Nutrition
HFS-811
200 C Street, SW
Washington, DC 20204

Sept. 15th, 2002

Dear Sir or Madam:

Pursuant to Section 6 of DSHEA and in accordance with 21 CFR Section 101.93(a)(2), the following is a notification to FDA that we will begin to market a dietary supplement in the U.S.A.

(1) The dietary supplement's name is YOUTH PLUS for women.
(2) The text of the function/structure statement on its label or labeling is: A dietary supplement that helps woman to revitalize her body's feminine activities and energy. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.
(3) The dietary ingredients: Ginseng, Blood Tonics, Prepared Rehmannia Root, Rehmannia Root, Chinese Cinnamon Bark, Dried Ginger, Spiny Amomum Fruit, Tree Peony Bark, Indian Bread, Water-plantain Tuber, Dogwood Fruit, Human Placenta, Licorice Root, Round Cardamom, Bighead Atractylodes Rhizome.
(4) Name and address of the manufacturer:
New York Healthy Herbs Inc.
135-23 40th Road Ste. 2F Flushing, NY 11354

The undersigned certifies that the information contained in this notice is complete and accurate and that New York Healthy Herbs Inc. has substantiation that the statement is truthful and not misleading. Two copies of this notification are enclosed.

Please contact me if you have any question pertaining to this notification.

Sincerely yours

Hui Fen Li
President

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